

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:)	Docket No.:	014835-101.02-029
Applicants:)	Conf. No.:	6557
Application No.:)	Art Unit:	2858
Date Filed:)	Examiner	Angela M Bertagna
Title:)	Customer No.:	24239
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DECLARATION OF INVENTORS IN U. S. PATENT APPLICATION NO. 10/536,502

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

CHRIS GEDDES, JOSEPH R. LAKOWICZ and LES BAILLIE severally and jointly hereby declare:

- 1) THAT We are co-inventors of the subject matter disclosed and claimed in United States Patent Application No. 10/536,502, filed December 14, 2005 in the United States Patent and Trademark Office entitled, "HIGH SENSITIVITY ASSAYS FOR PATHOGEN DETECTION USING METAL-ENHANCED FLUORESCENCE," claiming priority from PCT International Application No.: PCT/US03/38163 filed on November 26, 2003 which in turn claims priority to US Provisional Application No 60/429,263 filed on November 26, 2002, hereafter referred to as the "Application."
- 2) THAT the Application discloses and claims a system that includes the use of two separate and distinct probe sequences (a captured and free nucleotide sequence probes) that are not complementary to each other but instead are complementary to separate and distinct portions of

the target nucleotide sequence, which is anthrax. Importantly, with the specific use of two probes sequences that are complementary to different sections of the target nucleotide sequence, the free probe sequence includes a fluorophore that is positioned a distance from the metallic surface to provide for a more sensitive test with increased reliability even when the level of anthrax in the sample is not identifiable by other less sensitive tests.

- 3) THAT We are aware that the Application has been examined by the United States Patent and Trademark Office and aware that the claims of the Application have been rejected on various grounds including the disclosure of Cao, et al., Nanoparticles within Raman Spectroscopic Fingerprints for DNA and RNA Detection, Science, Aug 2002, Vol. 297, pp 1536-1540, hereinafter Cao.
- 4) THAT we have been informed by my legal representative that the rejections of the claims of the Application can be overcome by presenting evidence to the United States Patent and Trademark Office of our possession of the claimed invention prior to the August 30, 2002 publication date of the Cao reference (Publication Date).
- 5) THAT attached is Exhibit 1 hereof which is a true and exact copy of power point slide, with dates blackened out, that was created prior to the Publication Date for inclusion in a grant proposal. The slide clearly shows the use of two separate nucleotide sequence probes that have affinity for different sections of a target sequence of anthrax. Further, this slide shows that one of the probes may contain not only a fluorophore but also include a metal particle. Further included is Exhibit 2 which is a copy of the Disclosure and Record of Invention that was submitted after the Publication Date of Cao, where in the document states that the invention was reduced to practice. The provisional application relating to this invention was timely filed by November 26, 2002.
- 6) THAT we offer Exhibits 1 and 2 with this Declaration as evidence of the conception, diligence by us the inventors of the anthrax assay system of the present invention prior to the Publication date of August 30, 2002 and reduction to practice after the Publication date with a subsequent filing of a provisional application on November 26, 2002.

As a below-named declarant, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements, and the like, so made are punishable by fine or imprisonment, or both, under Section 1001 or Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Chris Geddes PhD

Date



Joseph R. Lakowicz, PhD

April 29, 2009

Date

Les Baillie, PhD

Date

As a below-named declarant, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements, and the like, so made are punishable by fine or imprisonment, or both, under Section 1001 or Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Chris Geddes PhD

Date

Joseph R. Lakowicz, PhD

Date



Les Baillie, PhD

16th APRIL 2004

Date

As a below-named declarant, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements, and the like, so made are punishable by fine or imprisonment, or both, under Section 1001 or Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Chris Geddes PhD

4-28-09

Date

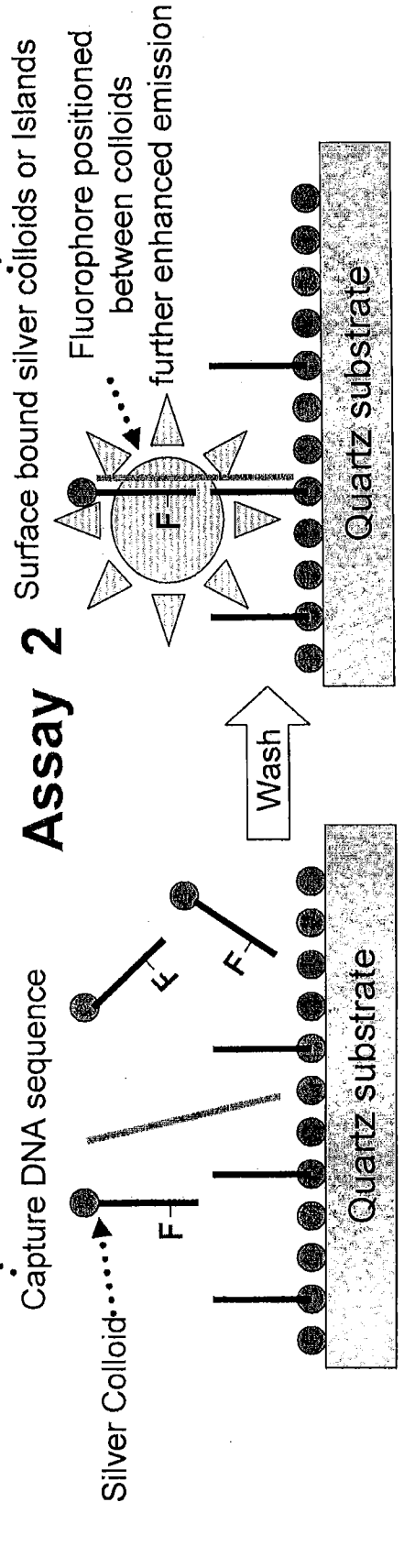
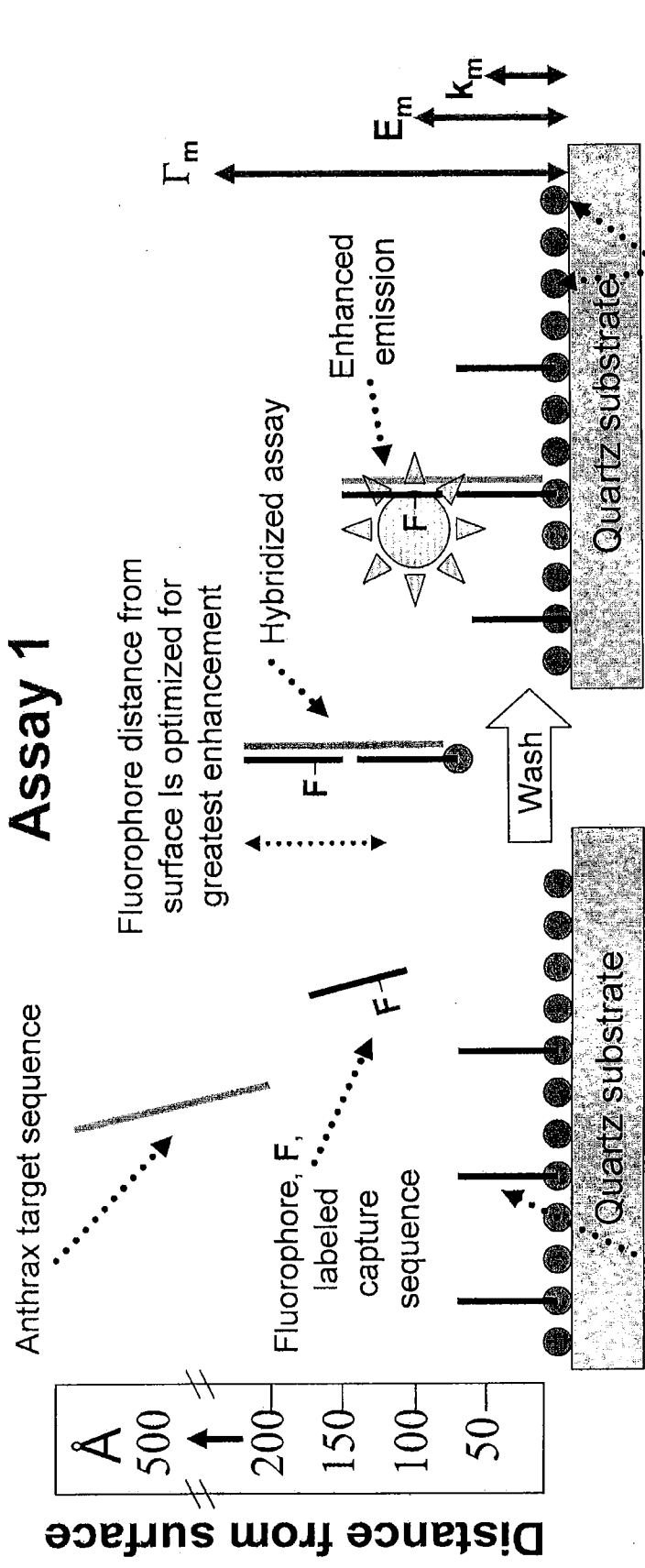
Joseph R. Lakowicz, PhD

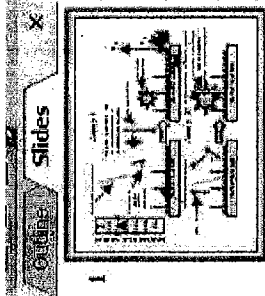
Date

Les Baillie, PhD

Date

Exhibit 1





Distance from surface

Silver

Assay scheme for grant (2).ppt Properties

General Summary Statistics Contents Custom

Created: [REDACTED]
Modified: [REDACTED]
Accessed: Thursday, August 07, 2008 9:53:22 AM
Printed:

Last saved by: Geddes Lab
Revision number: 1
Total editing time: 0 Minutes

Statistics:

Statistic name	Value
Slides:	1
Paragraphs:	40
Words:	72
Bytes:	28787
Notes:	1
Hidden slides:	0
Multimedia clips:	0
Presentation format:	On-screen Show

OK Cancel

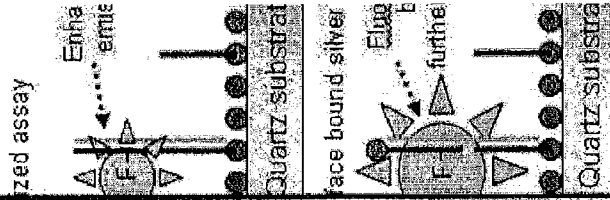


Exhibit 2

UNIVERSITY OF MARYLAND BIOTECHNOLOGY INSTITUTE (UMBI)

UMBI File No.

02-029-JDE

Date Received

DISCLOSURE AND RECORD OF INVENTION

This invention was made and/or reduced to practice in the course of work performed at the UMBI facility.
Mail completed disclosure to UMBI Patent Department, 701 E. Pratt Street, Suite 200, Baltimore, MD 21202
Telephone (410) 385-6324-25, if you have questions regarding this form.

Title of Invention:

High-Sensitivity Assays for Pathogen Detection using Metal-Enhanced Fluorescence

Please list names of those who contributed to the inventive thought and to the final result of the invention. If a patent application is filed the Patent Department will make a legal determination of inventorship.

<u>Contributor(s):</u>	<u>Full Name</u>	<u>Title/Position</u>	<u>Employer</u>	<u>Division</u>	<u>Phone No.</u>	<u>Mail Stop</u>
(40%)	Chris D. Geddes	Asst. Professor	UMBI	MBC	(410) 706 3149	
(40 %)	Joseph R. Lakowicz	Professor	UMAB	S of Medicine	(410) 706 4809	
(20 %)	Les Baillie	Assoc. Professor	UMBI	MBC	(410) 706 4565	

Contributor(s) Permanent Home Address(es):

<u>Name</u>	<u>Citizenship</u>	<u>Street Address</u>	<u>City, State, and Zip Code</u>
Chris D. Geddes	UK	15 Charles Plaza, #805,	Baltimore, MD, 21201
Les Baillie	UK	7356 Eden Brook Drive, #715,	Columbia, MD, 21046
Joseph R. Lakowicz	USA	10037 Fox Den Road	Ellicott City, MD, 21042

IMPORTANT - Check the funding source for this invention & provide the information requested:

☐ Government Grants

Funding Agency and Grant No. No Funding for this invention

☐ Principal Investigator

☐ Sponsored Research Grants

Sponsor Name

☐ Principal Investigator

☐ Private, Non-Government Grants

Funding Agency and Grant No.

Principal Investigator

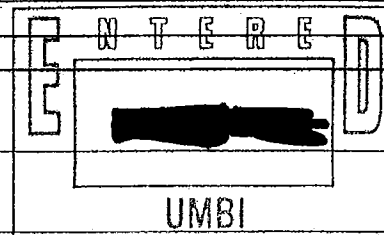
☐ Subcontract

Subcontract No.

Contractor

☐ Other

Describe



From what source do you reasonably expect future or continuing funding?

Source NIH Is this ☐ continuing funding or ☒ future funding?

☐ No future funding is currently expected. We have just submitted an R01 proposal to the NIH (attached).

Conception (Date, Place):

Earliest documentation of your invention: (please provide date and identify the document)

First Sketch or Drawing: Not Disclosed

First Written Description: Not Disclosed

Names of witnesses or others with knowledge of facts relating to conception:

Inventors _____

Reduction to Practice:

Date first model completed:

Date of operation and testing: **See 1 on attached sheet**

Place of test:

Results of testing:

Witnesses or others with direct knowledge of test:

Inventors _____

Important: WAS ANY PROPRIETARY MATERIAL FROM OUTSIDE YOUR LABORATORY USED TO DEVELOP YOUR INVENTION (e.g., software code, cell line, antibody, DNA fragments, or chemical compound)? If yes, please describe.

No

DESCRIPTION:

Background of the invention Please summarize:

- 1) Technical problems overcome to make the invention,
- 2) What your invention enables people to do that couldn't be done as well before,
- 3) How people currently address the problem your invention addresses.

See 2

Summary of the Invention Please include a sketch of the invention if possible (you may attach extra pages):

See 3

List uses of the invention - research, commercial, pilot plant, etc.; Think as broadly as possible.
Identify companies that might be interested in licensing this technology.

See 4

Publications (including UMBI reports, meeting abstracts, or prior patents or patent applications) that ACTUALLY DESCRIBE or RELATE to the invention:

<u>Title/Subject</u>	<u>Publication Date</u>	<u>Indicate "Describes" or "Relates" to Inv.</u>	<u>Journal and/or UMBI Rep. No. If prior UMBI pat. appl., Disclosure ID#</u>
<u>See attached list of patents and papers which relate to this invention disclosure</u>		<u>Relates</u>	

Papers you have SUBMITTED or are PREPARING for publication that describe or relate to your invention:

<u>Title/Subject</u>	<u>Anticipated Publ. Date</u>	<u>Indicate "Describes" or "Relates" to Inv.</u>	<u>Journal and/or UMBI Rep. No. If prior UMBI pat. appl., Disclosure ID #</u>
<u>No papers submitted or pending. However we have attached a recently submitted R01 grant proposal based on this disclosure.</u>			

Please notify the Patent Dept. (x 6324-25) if you later plan new publications that describe or relate to the invention.

I believe myself to have contributed to be the above-described invention. (Each contributor must sign.)

CONTRIBUTOR: (40% Contribution) Dr C. [Signature] DATE: [Redacted]
WITNESS: Mary Rosenthal DATE: [Redacted]
CONTRIBUTOR: (40% Contribution) [Signature] DATE: [Redacted]
WITNESS: Mary Rosenthal DATE: [Redacted]
CONTRIBUTOR: (20% Contribution) Dr L. [Signature] DATE: [Redacted]
WITNESS: Mary Rosenthal DATE: [Redacted]

Read and Understood by:

UMBI Patent Department Reviewer

Date: _____

[Signature]
Center's Director

Date: [Redacted]